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RESEARCH LETTER

Performance of the Novel Observation Group Criteria of the European Society of Cardiology (ESC) 0/1-Hour Algorithm in a Low-Risk Population

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The 2020 European Society of Cardiology (ESC) guidelines on non–ST-segment elevation acute coronary syndrome recommend a third high-sensitivity cardiac troponin (hs-cTn) measurement for patients assigned to the observation group by the ESC 0/1-hour algorithm.[1] Recently, novel 3-hour criteria for patients in the observation group were proposed for use in the emergency department.[2] In the OUT-ACS study (One-hour Troponin in a Low-Prevalence Population of Acute Coronary Syndrome), the diagnostic performance of the ESC 0/1-hour algorithm for hs-cTnT was prospectively validated among low-risk patients with chest pain in an emergency outpatient setting. Although demonstrating high efficacy and rule-out safety (Figure), 19.5% of the cohort was assigned to the indeterminate observation group where 15 patients had an acute myocardial infarction (MI).[3]

Motivated by the recently suggested criteria,[2] we investigated how the novel hs-cTnT thresholds may perform with a 4-hour interval among low-risk patients with chest pain in an emergency outpatient setting.

We used data from the observational OUT-ACS study (NCT02983123), conducted at an emergency outpatient clinic not based at a hospital, in Oslo, Norway, between 2016 and 2018.[3] Details of the study methodology are outlined in a previous publication.[3] Data supporting the following analysis are available from the corresponding author upon reasonable request. Patients considered at high risk of acute coronary syndrome were rapidly hospitalized and not included. Patients with chest pain regarded as low risk but needing a safe rule-out of MI were eligible for inclusion and serial hs-cTnT measurements at the clinic. Hs-cTnTs were sampled at 0, 1, and 4 hours and the samples were dispatched for analysis.[3] In this retrospective analysis, the 0- and 4-hour hs-cTnTs samples were used. Patients in the OUT-ACS observation group were re-assigned to either rule-out, rule-in, or further observation (Figure) by using a 4-hour interval in combination with the suggested hs-cTnT thresholds.[2]

The diagnostic performance was measured by the sensitivity, specificity, and negative and positive predictive values for acute MI, calculated using Stata 17.0 (Stata Corp, College Station, TX, USA). Acute MI was adjudicated by 2 cardiologists using the Third Universal Definition of MI,[4] which was applicable at the time of the study. A third cardiologist was involved in case of disagreements. Data on MI and deaths during the subsequent 90 days were obtained from the Norwegian Cardiovascular Disease Registry.[3] Study participation was based on written informed consent, and the OUT-ACS study was approved by the Regional Ethics Committee and Oslo University Hospital Information Security and Privacy Office.[3]

Key Words: acute coronary syndrome ■ acute myocardial infarction ■ chest pain ■ outpatient ■ troponin

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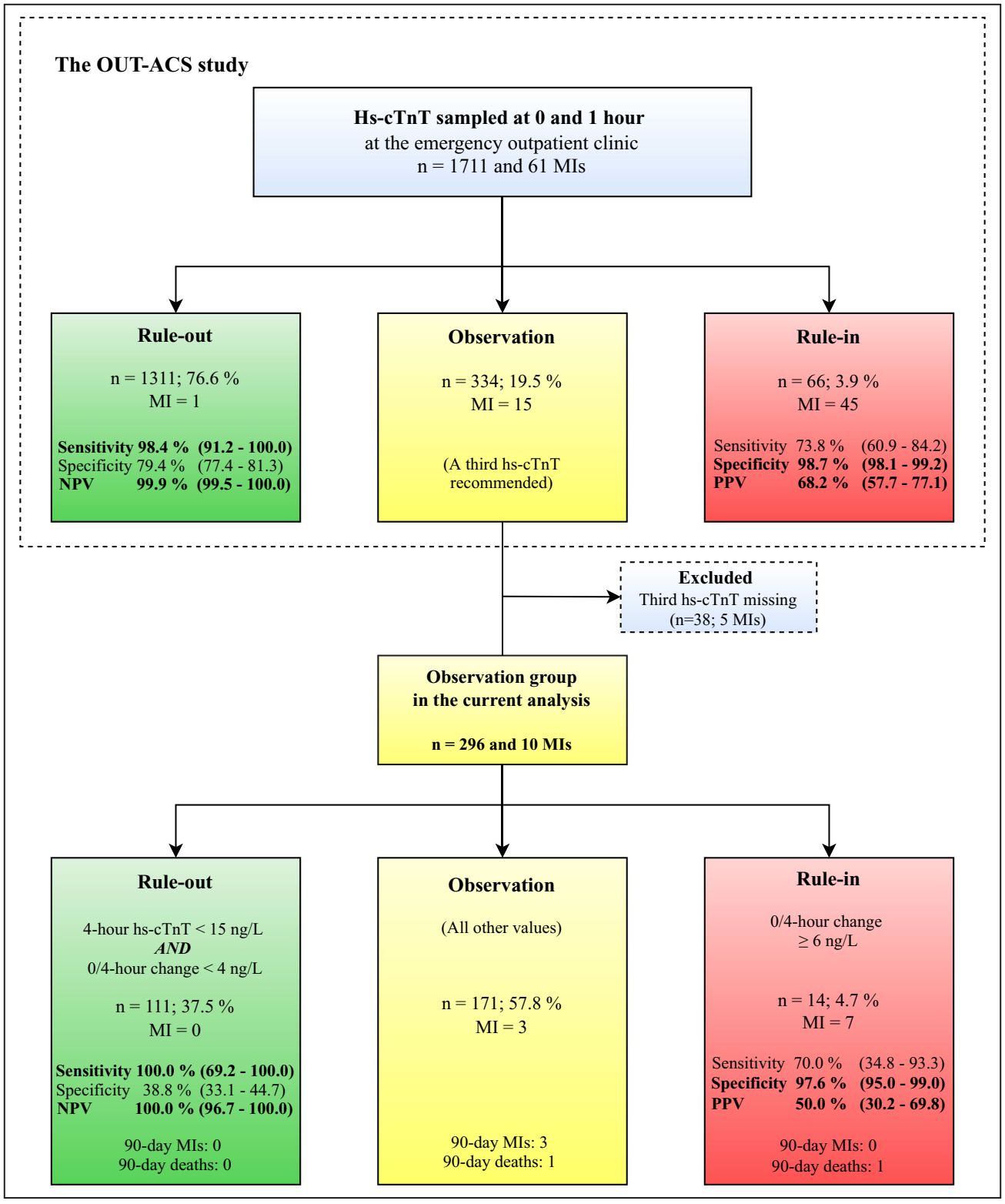

Figure. Diagnostic performance of the novel observation group criteria in a low-risk population.
The suggested hs-cTnT criteria for the observation group[2] were applied with a 0/4-hour interval. Results from the main OUT-ACS publication[3] are presented in the upper delineated panel. The corresponding 95% CIs are reported in parentheses. OUT-ACS indicates One-hour Troponin in a Low-Prevalence Population of Acute Coronary Syndrome; hs-cTnT indicates high-sensitivity cardiac troponin T; MI, myocardial infarction; NPV, negative predictive value; and PPV, positive predictive value.

In the OUT-ACS study, 334 of 1711 (19.5%) patients were assigned to the observation group (median age 72 years [IQR, 62–83]; 44.9% were female) by the ESC 0/1-hour algorithm.[3] Among them, 38 were excluded because of a missing 4-hour hs-cTnT measurement. Hence, this subanalysis encompasses 296 patients in the observation group, including 10 with an MI (Figure). The median 0/4-hour interval was 4.33 hours (interquartile range, 4.08–4.84). Applying the proposed thresholds,[2] 111/296 (37.5%) were assigned towards the rule-out group (Figure). The corresponding safety metrics sensitivity and negative predictive value were both 100.0%, with 95% CI, (69.2–100.0) and (96.7–100.0), respectively. None in the rule-out group experienced an MI or died during the following 90 days. Among the 14 patients triaged towards rule-in, 7 were diagnosed with an MI (specificity 97.6% [95% CI, 95.0–99.0] and positive predictive value 50.0% [95% CI, 30.2–69.8]). With only 171/1711 remaining in the observation group, the overall efficacy of the 0/1-hour algorithm increased to 90%.

High rule-out safety and increased overall efficacy were demonstrated by applying the newly suggested thresholds for the 0/1-hour observation group. Compared with Lopez-Ayala et al, the broader sampling interval between the measurements (0/4-hour) may have contributed to more patients being triaged upwards (from *rule-out* to *observation* and from *observation* to *rule-in*), thus increasing safety. Noticeably, the suggested 0/3-hour rule-in delta (≥6 ng/L)[2] is smaller than the delta validated for the ESC 0/2-hour hs-cTnT rule-in algorithm (≥10 ng/L)[1] Applied in a low-prevalence setting using a 4-hour window, the positive predictive value was lower than in the validation cohort (ie, 50.0% and 78.4%, respectively).[2] However, our results are limited by few events and high imprecision, as visualized by the broad CIs. Nevertheless, the results are encouraging in terms of reducing the number of patients remaining in the observation group. Compared with the rule-out group, patients in the observation group have higher age and cardiovascular risk.[1–3,5] We, therefore, believe it is advisable to consult a cardiologist for the remaining 10% in the observation group, either for direct hospital transfer or for a cardiac outpatient consultation. Because a safe MI rule-out strategy is essential in the outpatient setting, our results may illustrate the potential benefits of the observation group criteria if the ESC 0/1-hour algorithm is considered for future implementation in a low-risk setting. A larger study further exploring these findings is needed.

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